IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ABBVIE INC. and **ABBVIE DEUTSCHLAND GMBH & CO. KG,** **Plaintiffs,** **v.** **HON. DERRICK BRENT,** in his official role as Acting Under Secretary of Commerce For Intellectual Property and Acting Director of the United States Patent and Trademark Office, **Defendant.**	**Civil Action No. 24-2344**

COMPLAINT

Plaintiffs AbbVie Inc. and AbbVie Deutschland GMBH & Co. KG (hereinafter, "Plaintiffs" or "AbbVie"), by and through their undersigned counsel, for its Complaint against the Honorable Derrick Brent, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office, (hereinafter, "Director" or "Defendant"), respectfully state as follows:

NATURE OF ACTION

1. This is an action by AbbVie, the owner and assignee of United States Patent No. 11,369,599 ("the '599 patent") (attached as **Exhibit A**), entitled MELT-EXTRUDED SOLID DISPERSIONS CONTAINING AN APOPTOSIS-INDUCING AGENT. Pursuant to 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. §§ 701-706, AbbVie seeks a judgment that the patent term adjustment ("PTA") for the '599 patent was incorrectly calculated, and further requests relief to change the PTA for the '599 patent from 439 days to 568 days.

2. The invention described in the '599 patent is an orally deliverable pharmaceutical tablet containing the Bcl-2 inhibitor compound Venetoclax, which is the active ingredient in Plaintiffs' lifesaving anti-cancer drug Venclexta®, in essentially non-crystalline or amorphous form. Bcl-2 inhibitors act by restoring the process of cell death and inhibiting the expression of Bcl-2 proteins that promote cell survival, thus inducing the death of cancer cells. Venclexta® has been approved by the FDA to treat certain patients with chronic lymphocytic leukemia ("CLL"), small lymphocytic lymphoma ("SLL"), or acute myeloid leukemia ("AML").

3. As detailed hereinbelow, during the prosecution of the '599 patent the United States Patent and Trademark Office ("PTO") took an improper, since-withdrawn action that set in motion a series of events that ultimately led to an unwarranted reduction in the term of the '599 patent by 129 days. Contrary to Defendant's subsequent determinations, Plaintiffs' actions during prosecution were necessitated by the PTO's improper action, were expressly requested by the PTO's Examiner, and/or were steps taken to prevent abandonment of the application. Plaintiffs did not "fail[] to engage in reasonable efforts to conclude prosecution of the application" and, thus, no reduction of PTA is appropriate under 35 U.S.C. § 154(b)(2)(C).

4. Defendant erred in applying 37 C.F.R. § 1.704(c)(8) and the holdings of *Supernus Pharm., Inc. v. Iancu*, 913 F.3d 1351 (Fed. Cir. 2019) ("*Supernus*") and *Gilead Scis., Inc. v. Lee*, 778 F.3d 1341 (Fed. Cir. 2015) ("*Gilead II*") to the instant case. Alternatively, Defendant's application and interpretation of 37 C.F.R. § 1.704(c)(8) was arbitrary and capricious, and/or Defendant's promulgation of 37 C.F.R. § 1.704(c)(8) exceeded its statutory jurisdiction, authority, or limitations, in light of the language of 35 U.S.C. § 154(b)(2)(C).

5. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 154(b)(4)(A), and the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706.

THE PARTIES

6. Plaintiff AbbVie Inc. is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters located at 1 North Waukegan Road, North Chicago, Illinois 60064.

7. Plaintiff AbbVie Deutschland GMBH & Co. KG is a corporation organized and existing under the laws of Germany with a principal place of business at Mainzer Straße 81, 65189 Wiesbaden, Germany.

8. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to utilize its expertise, dedicated employees, and unique approach to innovation to achieve the goal of markedly improving treatments across therapeutic areas, including the treatment of hematological cancers such as non-Hodgkin's lymphoma ("NHL"), chronic lymphocytic leukemia ("CLL"), acute myeloid leukemia ("AML"), and others.

9. Defendant Derrick Brent is named in his official capacity as the Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the PTO. Defendant was appointed to the position of Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the PTO on August 1, 2022, and assumed his current acting roles upon the resignation of Director Katherine K. Vidal on December 13, 2024.

10. Defendant is the acting head of the PTO and is responsible for superintending and/or performing all duties required by law with respect to the granting and issuing of patents. As such, 35 U.S.C. § 154(b)(3)(B)(i) designates Defendant as the official responsible for

determining the period of Patent Term Adjustments. Defendant is also the official responsible for prescribing regulations establishing procedures for the determination of Patent Term Adjustments. 35 U.S.C. § 154(b)(3)(A).

JURISDICTION AND VENUE

11. This Court has jurisdiction over this action and is authorized to issue the relief sought pursuant to 28 U.S.C §§ 1331, 1338(a), and 1361; 35 U.S.C.§ 154(b)(4)(A); and 5 U.S.C. §§ 701-706.

12. Venue is proper in this district under 35 U.S.C. § 154(b)(4)(A) and 28 U.S.C. § 1391(e)(1).

13. This action is timely filed in accordance with 35 U.S.C. § 154(b)(4)(A) because it is being filed within 180 days after the Defendant's Decision on AbbVie's Request for Reconsideration (attached as **Exhibit B**), dated July 19, 2024.

BACKGROUND ALLEGATIONS COMMON TO ALL COUNTS

The '599 Patent

14. United States patent application No. 14/340,435 ("the '435 application") was filed on July 24, 2014, and issued as the '599 patent on June 28, 2022.

15. AbbVie Inc. and AbbVie Deutschland GMBH & Co KG are the assignees of the entire right, title, and interest in the '599 patent, as evidenced by records on deposit with the PTO and the face of the '599 patent.

Initial Prosecution History of the '435 Application

16. During prosecution of the '435 application, on June 19, 2015, an Examiner of the PTO issued a Nonfinal Office Action ("the June 19, 2015 Office Action") that included the following Restriction Requirement:

- Group I: Claims 1-31 and 45, drawn to compositions, classified in class 514, subclass 183;
- Group II: Claims 32-44, drawn to methods of preparing compositions, classified in class 514, subclass 183; and
- Group III: Claims 46-56, drawn to methods of treatment, classified in class 514, subclass 183.

17. Additionally, the June 19, 2015 Office Action indicated that the application contained claims directed to the following patentably distinct species: "the various compounds of formula I and disclosed diseases."

18. The June 19, 2015 Office Action noted that AbbVie's patent counsel had made a provisional election to the claims of Group I, and the compound 4-(4-{[2-(4-chlorophenyl)-4,4-dimethylcyclohex-l-en-l-yl]methyl}piperazin-1-yl)-N-({3-nitro-4-[(tetrahydro-2H-pyran-4-ylmethyl)amino]phenyl}sulfonyl)-2-(1H-pyrrolo[2,3-b]pyridin-5-yloxy)benzamide (hereinafter, "ABT-199," the compound recited in originally-filed Claim 10, which depended from Claim 1).

19. Claim 45, which was included in the claims of Group I, was at that time directed to an orally deliverable pharmaceutical dosage form (such as a tablet) comprising the solid dispersion of Claim 1.

20. AbbVie filed an Amendment on September 18, 2015, formally electing the claims of Group I and amending the scope of Claim 1 to more specifically read on the elected compound, ABT-199. The scope of Claim 45 was not changed.

21. The Examiner issued an Election of Species Requirement on January 5, 2016, indicating that the application contained claims directed to the following patentably distinct

species: (a) the various disclosed polymeric carriers, (b) the various disclosed surfactants, and (c) the various disclosed glidants.

22. At that time, Claim 1 referred to a polymeric carrier and a surfactant, but it did not refer to a glidant. A glidant was referenced only in dependent claims.

23. AbbVie filed a Response on March 4, 2016, electing copovidone as the polymeric carrier, polysorbate as the surfactant, and silicon dioxide as the glidant.

24. The Examiner issued a Final Office Action on June 28, 2016 ("the June 28, 2016 Final Office Action"), rejecting all pending claims for obviousness-type double patenting. No further reference was made to the Restriction Requirement or the Election of Species Requirements in the June 28, 2016 Final Office Action or any of the following prosecution filings:

- the RCE/Amendment filed on October 28, 2016;
- the Nonfinal Office Action issued on September 7, 2017;
- the Amendment filed December 7, 2017, which narrowed the scope of the active ingredient in Claim 1 to specifically reference ABT-199 but did not otherwise alter the claim;
- the Final Office Action issued on April 5, 2018;
- the RCE/Amendment filed on June 5, 2018;
- the Nonfinal Office Action issued on August 9, 2019; and
- the Amendment filed on November 8, 2019.

25. In the Nonfinal Office Action that issued on August 9, 2019, the Examiner withdrew the obviousness-type double patenting rejection, but, for the first time, raised 35 U.S.C. § 101 and § 112 rejections based on the phrase "as observed by X-ray diffraction analysis," as used in claim 1's recitation of "wherein the solid dispersion comprises less than 5% of the compound or pharmaceutically acceptable salt thereof in crystalline form, as observed by X-ray diffraction

analysis." The Office Action also raised a 35 U.S.C. §§ 112 rejection based on the phrase "a parent-compound-equivalent."

26. AbbVie filed an Amendment on November 8, 2019 to address these 35 U.S.C. § 101 and § 112 rejections by removing (a) the phrase "wherein the solid dispersion comprises less than 5% of the compound or pharmaceutically acceptable salt thereof in crystalline form, as observed by X-ray diffraction analysis" from claim 1, and (b) the phrase "a parent-compound-equivalent" from other pending claims. In addition, pending claim 1 was further amended to recite an orally deliverable pharmaceutical tablet comprising a solid dispersion, consistent with claim 45, that was included in the claims of Group I by the Restriction Requirement. Claim 1 was further amended to remove the recitation of a surfactant and to more particularly claim the invention, for example by inserting concentration ranges of the compound.

27. The Amendment dated November 8, 2019 was fully responsive to the Office Action. Amendments to Claim 1 were made to both narrow the scope of the claim in order to more particularly claim the invention and to eliminate the claim language that the Examiner relied upon as the basis for the 35 U.S.C. § 101 and § 112 rejections. The Amendment also included pending claims that remained consistent with the search strategies used by the PTO to date. As such, no additional burden was placed on the PTO to continue examination.

The PTO Issues an Improper Notice of Non-Responsive Amendment

28. On February 12, 2020, in response to the Amendment dated November 8, 2019, the PTO issued a Form PTO-90 that contained a Notice of Non-Responsive Amendment (attached as **Exhibit C**).

29. In the Notice of Non-Responsive Amendment, the Examiner incorrectly claimed that AbbVie's prior Amendment "shifted to an independent and distinct invention" that had a "materially different design" from the originally claimed invention. According to the Examiner:

> [T]he amended claim (Invention I) is drawn to an orally deliverable pharmaceutical tablet comprising a solid dispersion comprising (a) the claimed compound; (b) at least one water soluble polymeric carrier wherein "a single dose of the compound delivered by oral administration of one or more tablets to a population of non-fasting adult humans…" whereas the originally examined claim (Invention II) was drawn to a solid dispersion comprising the claimed compound dispersed in a solid matrix that comprises (a) at least one water soluble polymeric carrier and (b) at least one surfactant.

30. The Notice gave AbbVie two months to respond and "supply the omission or correction to avoid abandonment."

31. On March 13, 2020, AbbVie's patent counsel participated in an interview with the Examiner. According to the Affidavit of AbbVie's patent counsel Derick Allen submitted to the PTO during prosecution (attached as **Exhibit D**), during the interview AbbVie explained to the Examiner why the Notice was improper, highlighting that the amended claims were within the scope of the previous election. The Examiner stated, however, that she would only consider withdrawing the Notice if AbbVie filed a Response. The Examiner discussed with AbbVie's counsel potential claims that she believed would be compliant with the Notice of Non-Responsive Amendment.

AbbVie Successfully Petitions Defendant to Withdraw the Improper Notice

32. AbbVie continued to believe that the Notice of Non-Responsive Amendment was improper, and on March 16, 2020, filed a Petition under 37 C.F.R. § 1.181 to Withdraw Notice of Non-Responsive Amendment. The Petition sought the Defendant's involvement in the case in order to overrule the Examiner and withdraw the Notice.

33. Unable to predict when the Defendant would act on the Petition, and knowing that the Notice set a two-month period for response after which the application would be considered abandoned, AbbVie also filed an Amendment and Response to Non-Final Office Action and Notice of Non-Responsive Amendment on the same day. AbbVie specifically stated in the Amendment that it was being filed "as a precaution to ensure the present application remains pending" and to "preserve Applicant's rights in view of the Petition." The Amendment added new claim 111, the content of which was discussed during the March 13, 2020 interview "during which [the Examiner] had indicated that such a claim would be found responsive."

34. On March 19, 2020, the PTO issued a Petition Decision granting the request to withdraw the Notice of Non-Responsive Amendment. The Petition decision directed the Examiner to act on AbbVie's November 8, 2019 Amendment.

35. On June 10, 2020, the Examiner issued a Final Office Action in response to AbbVie's March 16, 2020 Amendment.

Issuance of the '599 Patent and Incorrect Determination of Patent Term Adjustment

36. Following subsequent prosecution of the '435 application, the PTO issued the '599 patent on June 28, 2022. In the Issue Notification, the PTO incorrectly stated that the PTA due the '599 patent was 231 days, an error that appears on the face of the patent.

37. AbbVie promptly filed an Application for Patent Term Adjustment After Issuance Pursuant to 37 C.F.R. § 1.705 on July 5, 2022. In the Application, AbbVie explained to the PTO why the correct PTA calculation should be 568 days.

38. On February 1, 2024, the PTO issued a Petition Decision on the Application for Patent Term Adjustment redetermining the PTA to be 439 days. The Decision agreed with AbbVie's calculation of PTA on all points save one: the PTO calculated a PTA reduction of

129 days due to alleged applicant delay, the period between the November 8, 2019 Amendment and the March 16, 2020 Amendment.

39. On April 30, 2024, AbbVie again sought Defendant's involvement in the matter, and filed a Renewed Request for Reconsideration and Recalculation of Patent Term Adjustment under 37 C.F.R. § 1.705 and Petition under 37 C.F.R. § 1.181(A)(3) to Invoke the Supervisory Authority of the Director (attached as **Exhibit E**). The Renewed Request explained to Defendant why the correct PTA calculation for the '599 patent should be 568 days, and why the PTO's calculation of 439 days was incorrect.

40. On July 19, 2024, the PTO issued a Petition Decision on the Renewed Request for Reconsideration and Recalculation of Patent Term Adjustment under 37 C.F.R. § 1.705 and Petition under 37 C.F.R. § 1.181(A)(3) to Invoke the Supervisory Authority of the Director. The Decision denied AbbVie's Petition and maintained the calculation of PTA as 439 days.

Patent Term Guarantee

41. The Patent Term Guarantee Act of 1999, a part of the American Inventors Protection Act ("AIPA"), amended 35 U.S.C. § 154(b) to address concerns that delays by the PTO during the prosecution of patent applications could result in a shortening of the effective life of the resulting patents to less than seventeen years. The amendments created patent term adjustment, commonly referred to as PTA, a means of adjusting patent term to account for delays at the PTO.

42. Patent term adjustment applies to original utility patent applications (including continuations, divisionals, and continuations-in-part) filed on or after May 29, 2000.

43. In calculating PTA, Defendant must take into account PTO delays under 35 U.S.C. § 154(b)(1), any overlapping periods in the PTO delays under 35 U.S.C. § 154(b)(2)(A), and any applicant delays under 35 U.S.C. § 154(b)(2)(C).

44. Under 35 U.S.C. § 154(b)(1)(A), an applicant is entitled to PTA for the PTO's failure to carry out certain acts during processing and examination within defined deadlines ("A Delay").

45. Reduction of the period of adjustment is subject to limitations under 35 U.S.C. § 154(b)(2), including 35 U.S.C. § 154(b)(2)(C)(i), which states "[t]he period of adjustment of the term of a patent under paragraph [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application" ("C Reduction").

46. 35 U.S.C. § 154(b)(2)(C)(iii) states that "[t]he Director shall prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application."

47. The PTO promulgated 37 C.F.R § 1.704(c) to identify "[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances," and included among those circumstances the following: "(8) Submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed."

48. Under 35 U.S.C. § 154(b)(4)(A), "[a]n applicant dissatisfied with the Director's decision on the applicant's request for reconsideration under paragraph (3)(B)(ii) shall have exclusive remedy by a civil action against the Director filed in the United States District Court for

the Eastern District of Virginia within 180 days after the date of the Director's decision on the applicant's request for reconsideration. Chapter 7 of title 5 shall apply to such action."

Proper Calculation of Patent Term Adjustment for the '599 Patent

49. Under 35 U.S.C. § 154(b)(2)(C)(i), "[t]he period of adjustment of the term of a patent under [154(b)(1)] shall be reduced by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

50. In the instant case, by filing the Amendment and Response on March 16, 2020, as a precautionary measure to ensure that the application did not become abandoned while the Defendant considered its concurrently-filed Petition challenging the improper Notice of Non-Responsive Amendment, AbbVie did not fail to engage in reasonable efforts to conclude prosecution. Because no action or inaction by the applicant during this period can be characterized as failure "to engage in reasonable efforts to conclude prosecution," the calculation of Applicant Delay cannot include at least these 129 days.

51. The PTO's determination that the Amendment and Response of March 16, 2020 was a "supplemental reply or other paper" within the scope of 37 C.F.R. § 1.704(c)(8) is arbitrary and capricious and inconsistent with the PTO's other regulations including 37 C.F.R. § 1.111(a)(2).

52. The PTO's determination that the Amendment and Response of March 16, 2020 was not "expressly requested by the examiner" as set forth in 37 C.F.R. § 1.704(c)(8) is arbitrary and capricious in view of the Examiner's requirement that a response to the Notice of Non-Responsive Amendment be filed within two months.

53. The PTO's reduction of PTA by 129 days as Applicant Delay is arbitrary and capricious in view of the clear and unambiguous language under 35 U.S.C. § 154(b)(2)(C)(i),

which only permits the reduction "by a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

54. The correct PTA for the '599 patent is 568 days, consisting of 690 days of A Delay by the PTO, reduced by 122 days of C Delay by AbbVie, but eliminating the additional C Delay of 129 days that was improperly assessed by Defendant.

Defendant's Abrogation of the Patent Term Guarantee

55. Defendant has improperly calculated the PTA for the '599 patent in a manner that deprives AbbVie of the full amount of A Delay, because Defendant reduced the accrued PTA by an amount that exceeded the general limitation on PTA reduction as set forth at 35 U.S.C. § 154(b)(2)(C)(i).

56. Defendant has inappropriately relied upon 37 C.F.R. § 1.704(c)(8) to support its flawed calculation of PTA. Defendant's determination that the March 16, 2020 Amendment and Response was a "supplemental reply or other paper" that was not "expressly requested" by the Examiner is in error and plainly contrary to the clear and unambiguous language of 35 U.S.C. § 154(b)(2)(c)(i).

57. Defendant has also improperly applied the *Supernus* decision in a manner inconsistent with 35 U.S.C. § 154(b)(2)(c)(i). *Supernus* held that "[a] period of time including no identifiable efforts that could have been undertaken" by the applicant to advance or conclude prosecution "cannot be 'equal to' the period of failure to undertake reasonable efforts under the terms of" 35 U.S.C. § 154(b)(2)(c)(i). Defendant has applied 37 C.F.R. § 1.704(c)(8) without identifying any reasonable effort Defendant could have taken instead of filing the March 16, 2020 Amendment and Response as a precautionary measure to avoid abandonment while awaiting Defendant's Decision on its concurrently-filed Petition.

58. Because Defendant's application of 37 C.F.R. § 1.704(c)(8) conflicts with the clear and unambiguous language of 35 U.S.C. § 154(b)(2)(C), *Gilead II*, and *Supernus,* AbbVie seeks correction of the PTA to reflect an additional 129 days of PTA.

COUNT 1
Action for Adjustment of Patent Term under 35 U.S.C. § 154(b)

59. The allegations of paragraphs 1–58 are incorporated in this claim for relief as if fully set forth herein.

60. The PTO did not comply with 35 U.S.C. § 154(b)(2)(C) in determining the reduction of Plaintiffs' patent term adjustment, and thus unfairly deprived Plaintiff of the amount of A Delay to which Plaintiffs are entitled pursuant to 35 U.S.C. § 154(b)(1)(A).

61. The PTO incorrectly applied 37 C.F.R.§ 1.704(c)(8), *Gilead II*, and *Supernus* when calculating the PTA for the '599 patent, resulting in an incorrect calculation of PTA that deprived Plaintiffs of the full and appropriate term of the '599 patent, and in a manner contrary to 35 U.S.C. § 154(b)(2)(C).

62. Reduction of the PTA period by 129 days as Applicant Delay, as a result of Plaintiffs filing an Amendment and Response to Non-Final Office Action and Notice of Non-Responsive Amendment on March 16, 2020, is inconsistent with 35 U.S.C. § 154(b)(2)(C)(i).

63. Plaintiffs' filing of an Amendment and Response on March 16, 2020 as a precautionary measure to ensure the '435 application remained pending while awaiting Defendant's decision on its Petition, also filed on March 16, 2020, did not, and could not, cause any actual delay or in any way impede examination.

64. Plaintiffs made reasonable efforts to conclude prosecution by filing an application with the PTO, which efforts were frustrated by delayed prosecution by the PTO.

65. Plaintiffs are entitled to an additional 129 days of PTA for the '599 patent.

66. The Court should Order that the 439 days of PTA determined by the PTO should be corrected to the full 568 days to which AbbVie is entitled by statute.

COUNT 2
Final Agency Action in Violation of 5 U.S.C. § 706(2)(A)

67. The allegations of paragraphs 1–66 are incorporated in this claim for relief as if fully set forth herein.

68. The PTO is an agency of the United States government. Judicial review of PTO action is not precluded and is expressly permitted by statute. The calculation of patent term is determined by statute and is not committed to the PTO's discretion.

69. The PTO's application of 37 C.F.R.§ 1.704(c)(8), *Gilead II*, and *Supernus* to the facts of this case is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A) because it produces the unfair and irrational result of penalizing Plaintiff for taking actions necessary to address the PTO's unwarranted issuance of a Notice of Non-Responsive Amendment, which Defendant ultimately conceded was improper and withdrew. The PTO's reduction of PTA by 129 days undermines the intent of 35 U.S.C. § 154(b)(2)(C)(i) to limit a reduction of period of adjustment "to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

70. Defendant's determination, inconsistent with 37 C.F.R. §1.111(a)(2) that the Amendment and Response to Non-Final Office Action and Notice of Non-Responsive Amendment dated March 16, 2020 was a "supplemental reply or other paper" that required an assessment of 129 days of applicant delay under 37 C.F.R. § 1.704(c)(8), is arbitrary and capricious, and has resulted in the improper calculation of PTA for the '599 patent.

71. Defendant's determination and conclusion that the Amendment and Response to Non-Final Office Action and Notice of Non-Responsive Amendment dated March 16, 2020 was not filed to advance and conclude prosecution under 37 C.F.R. §1.704(c), and therefore comprised applicant delay, is arbitrary and capricious and is an abuse of discretion, or is otherwise not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A).

72. Defendant's determination of PTA for the '599 patent on July 19, 2024, under 35 U.S.C. § 154(b)(3)(B)(ii), is a final agency action and is reviewable by a district court in accordance with 35 U.S.C. § 154(b)(4)(A) and 5 U.S.C. § 704. Plaintiff has been afforded no adequate remedy at law for Defendant's determination of PTA for the '599 patent.

73. Plaintiffs have exhausted all of the available administrative remedies under 35 U.S.C. § 154(b)(3)(A)-(B) or, in the alternative, pursuit of any further administrative remedies is futile.

74. Plaintiffs, as assignees of the '599 patent, have suffered legal wrong because of the PTO's actions in miscalculating the term of the '599 patent and failing to provide an adequate remedy for correction of such miscalculation. Plaintiffs are, and have been, adversely affected and aggrieved by such actions. There is no adequate remedy available to Plaintiffs, either administratively through the PTO or in any other forum, other than this Court. Plaintiffs will suffer irreparable injury if Defendant is not directed to recalculate PTA for the '599 patent.

75. An order directing Defendant to recalculate PTA for the '599 patent would not substantially injure any other interested parties, and the public interest will be furthered by correcting a procedural action that is contrary to law.

76. Plaintiffs are entitled to additional patent term for the '599 patent, such that the 439 days of PTA granted by the PTO should be corrected by the Court to reflect 568 days.

COUNT 3
Final Agency Action in Violation of 5 U.S.C. § 706(2)(C)

77. The allegations of paragraphs 1–76 are incorporated in this claim for relief as if fully set forth herein.

78. Under the APA, the Court "shall … hold unlawful and set aside" final agency action found to be "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C).

79. The PTO's promulgation of 37 C.F.R. § 1.704(c)(8) is a final agency action "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" because it is contrary to the express language of 35 U.S.C. § 154(b)(2)(C)(i) and (iii) and Congressional intent in enacting the PTA statute.

80. In granting Defendant the authority under 35 U.S.C. § 154(b)(2)(C)(iii) to "prescribe regulations establishing the circumstances that constitute a failure of an applicant to engage in reasonable efforts to conclude processing or examination of an application," Congress did not authorize Defendant to exceed the limitation of 35 U.S.C. § 154(b)(2)(C)(i) that any reduction in PTA be for "a period equal to the period of time during which the applicant failed to engage in reasonable efforts to conclude prosecution of the application."

81. To the extent that prior decisions upholding rulemaking of the PTO under 35 U.S.C. § 154(b)(2)(C)(iii), such as *Gilead II* or *Supernus*, relied on deference to the PTO under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), such deference is no longer appropriate under *Loper Bright Enterprises v. Raimondo*, 603 U.S. ___ (2024).

82. By "independently interpret[ing] the statute and effectuat[ing] the will of Congress subject to constitutional limits" under *Loper Bright*, this Court will "fix the boundaries of delegated

authority" granted to the PTO by Congress under 35 U.S.C. § 154(b)(2)(C)(iii). As promulgated and interpreted by the PTO, 37 C.F.R. § 1.704(c)(8) falls outside these boundaries.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray that this Court:

A. Conclude, pursuant to 35 U.S.C. §154(b)(1)(C), that Defendant's application of 37 C.F.R. 1.704(c)(8), is invalid and contrary to law, and the correct amount of PTA for the '599 patent is 568 days;

B. Enter a final judgment correcting the PTA for the '599 patent from the currently-calculated 439 days to the correct figure of 568 days, in accordance with 35 U.S.C. §154(b)(1)(C)(iii), and requiring the Defendant to alter the term of the '599 patent to reflect such additional PTA;

C. Find that 37 C.F.R. § 1.704(c)(8) is an unlawful exercise of power by Defendant falling outside the scope of Defendant's statutory authority and must be set aside; and

D. Grant such other and further relief as the nature of the case may admit or require and as may be just and equitable.

Date: December 23, 2024

Respectfully submitted,

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